Docket No.: 4518-0107PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hans LOIBNER et al.

Application No.: 10/519,323 | Confirmation No.: 9319

Filed: December 23, 2004 | Art Unit: 1643

For: PREPARATION BASED ON AN ANTIBODY DIRECTED AGAINST A TUMOR-ASSOCIATED GLYCOSYLATION SUCH AS LEWIS STRUCTURES | Examiner: NATARAJAN, Meera

STATEMENT OF THE INTERVIEW

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:
Applicants thank the Examiners for graciously agreeing to the interview. Applicants provide their statement of the interview and remarks below.

Remarks begin on page 2 of this paper.

Applicant's Summary of Examiner Interview, Tuesday April 22, 2008, 12:00.

Claims Discussed

Applicants presented claims 2, 35, 36, and 48 for substantive discussion.

Specific Prior Art Discussed

Applicants discussed prior art references Saleh and Basu. The new limitation of said antibody not inhibiting binding of its ligand (EGF) overcomes the prior art reference Saleh et al. Thus Applicants submit that the amendments filed February 25, 2008 overcome the prior art rejection and request the Examiner allow the pending claims.

Other Pertinent Matters Discussed

Claim 35

The Examiners asked whether the antibodies disclosed in the application are publicly available. In reply, Applicants herein provide information regarding the availability of antibodies ABL364 and IGN311. Applicants point out that the specification discloses that ABL364 was obtained from Novartis. Specification page 12, line 35. The specification discloses that IGN311 was produced for the assignee, Igeneon, under GMP conditions by BioInvent. *Id.* Applicants indicate that IGN311 has been widely described in the literature (Google reference provided) and is currently in clinical trials.

Applicants request that, in light of the pending claims and the present discussion, the Examiner withdraw all rejections.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: MAY 12 2008

Respectfully submitted,

By _____

Leonard R. Svensson
Registration No.: 30,330
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive
Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicant

Items 1 - 8 of 8 One page.

1: Schuster M, Jost W, Mudde GC, Wiederkum S, Schwager C, Janzek E, Altmann F, Stadlmann J, Stemmer C, Gorr G. Related Articles, Links

In vivo glyco-engineered antibody with improved lytic potential produced by an innovative non-mammalian expression system.
Biotechnol J. 2007 Jun;2(6):700-8.
PMID: 17427997 [PubMed - indexed for MEDLINE]

2: Antes B, Amon S, Rizzi A, Wiederkum S, Kainer M, Szolar O, Fido M, Kircheis R, Nechansky A. Related Articles, Links

Analysis of lysine clipping of a humanized Lewis-Y specific IgG antibody and its relation to Fc-mediated effector function.
J Chromatogr B Analyt Technol Biomed Life Sci. 2007 Jun 1;852(1-2):250-6. Epub 2007 Jan 26.
PMID: 17296336 [PubMed - indexed for MEDLINE]

3: Nechansky A, Schuster M, Jost W, Siegl P, Wiederkum S, Gorr G, Kircheis R. Related Articles, Links

Compensation of endogenous IgG mediated inhibition of antibody-dependent cellular cytotoxicity by glyco-engineering of therapeutic antibodies.
Mol Immunol. 2007 Mar;44(7):1815-7. Epub 2006 Oct 2.
PMID: 17011625 [PubMed - indexed for MEDLINE]

4: Farhan H, Schuster C, Klinger M, Weisz E, Waxenecker G, Schuster M, Sexl V, Mudde GC, Freissmuth M, Kircheis R. Related Articles, Links

Inhibition of xenograft tumor growth and down-regulation of ErbB receptors by an antibody directed against Lewis Y antigen.
J Pharmacol Exp Ther. 2006 Dec;319(3):1459-66. Epub 2006 Sep 8.
PMID: 16963623 [PubMed - indexed for MEDLINE]

5: Szolar OH, Stranner S, Zinoecker I, Mudde GC, Himmler G, Waxenecker G, Nechansky A. Related Articles, Links

Qualification and application of a surface plasmon resonance-based assay for monitoring potential HAHA responses induced after passive administration of a humanized anti Lewis-Y antibody.
J Pharm Biomed Anal. 2006 Jun 16;41(4):1347-53. Epub 2006 Apr 27.
PMID: 16644171 [PubMed - indexed for MEDLINE]

6: Kristelein H. Related Articles, Links

IGN-311. Igeneon.
Curr Opin Investig Drugs. 2005 Dec;6(12):1272-9.
PMID: 16370394 [PubMed - indexed for MEDLINE]

7: Schuster M, Umana P, Ferrara C, Brünker P, Gerdes C, Waxenecker G, Wiederkum S, Schwager C, Loibner H, Himmler G, Mudde GC. Related Articles, Links

Improved effector functions of a therapeutic monoclonal Lewis Y-specific antibody by glycoform engineering.
Cancer Res. 2005 Sep 1;65(17):7934-41.
PMID: 16140965 [PubMed - indexed for MEDLINE]

8: Klinger M, Farhan H, Just H, Drobny H, Himmler G, Loibner H, Mudde GC, Freissmuth M, Sexl V. Related Articles, Links

Antibodies directed against Lewis-Y antigen inhibit signaling of Lewis-Y modified ErbB receptors.
Cancer Res. 2004 Feb 1;64(3):1087-93.
PMID: 14871842 [PubMed - indexed for MEDLINE]

Items 1 - 8 of 8 One page.

Display Summary Show 20 Sort By Send to

Google Scholar BETA IGN311 Suche Erweiterte Scholar-Suche Scholar-Einstellungen Scholar-Hilfe

Web-Suche Suche Seiten auf Deutsch

Scholar **Alle Artikel** - **Zuletzt aufgerufene Artikel** Ergebnisse **11** - **20** von ungefähr **58** für **IGN311**. (**0,06** Sekunden)

A phase I/II, open label trial of Lewis Y specific monoclonal antibody **IGN311** to evaluate safety and ... - Alle 8 Versionen »
T Bauernhofer, H Samonigg, P Regitnik, B Lileg, W ... - Journal of Clinical Oncology, 2006 - opl.asco.org
A phase I/II, open label trial of Lewis Y specific monoclonal antibody **IGN311** to evaluate safety and efficacy in patients with malignant effusion. ...
Im Cache - Websuche

Immunological Assays to Differentiate Clinical Responders From Non-responders After CTLA4 Blockade ...
B Comin-Anduix, Y Lee, J Jalil, P de la Rocha, E ... - Journal of Immunotherapy, 2006 - immunotherapy-journal.com
... ANTIBODIES A Phase I/II, Open Label Trial With the Lewis Y Specific Humanized Monoclonal Antibody **IGN311** in Patients With Malignant Effusions Hans Loibner 1 , ...
Websuche

Objective Responses Induced by the Anti-CTLA4 Monoclonal Antibody CP-675,206 in Patients With ...
C Bulanhagui, D Pavlov, A Ribas, LH Camacho, J ... - Journal of Immunotherapy, 2006 - immunotherapy-journal.com
... ANTIBODIES A Phase I/II, Open Label Trial With the Lewis Y Specific Humanized Monoclonal Antibody **IGN311** in Patients With Malignant Effusions Hans Loibner 1 , ...
Websuche

[ZITATION] IGN312: Increased effector functions of a monoclonal antibody by glycoform engineering.
M Schuster, P Umana, P Brunker, G Himmler, G Mudde ... - AACRMTG, 2004 - American Association for Cancer Research
Websuche

A Phase I Trial of a Monoclonal Antibody Directed to Lewis Y.
D Oruzio, G Schlimok, N Eller, C Aulmann, S ... - Journal of Immunotherapy, 2004 - immunotherapy-journal.com
... Introduction: **IGN311** is a fully humanized monoclonal antibody targeting tumors with over-expression of Lewis Y. 60–90% of human carcinomas of epithelial ...
Websuche

Inhibition of signaling via erbB-receptors by antibodies that target the Lewis Y-antigen - Alle 7 Versionen »
G Waxenecker, M Klinger, H Farhan, M Freissmuth, G ... - Cancer Cell International, 2004 - cancerci.com
... Introduction. **IGN311** is a humanized monoclonal IgG1 antibody that binds to the Lewis Y (LeY) carbohydrate overexpressed on epithelial cancers. ...
Im Cache - Websuche

Optimization of a Fed-batch Strategy for Production
P Hinterleitner, P Ganglberger, B Obermüller, B ... - Springer
... Key words: Feeding strategy, fed batch, small scale, roller bottles, bench-top bioreactor, consumption rates, SP2/0, **IGN311**, hydrolysate, Hypep 4601, product ...
Websuche

Enhanced Tumor Inhibition of MDA-MB-231 Breast Carcinoma by the Anti-Tissue Factor Antibody, CNTO ...
C Ngo, B Scallon, R Tawadros, F McCabe, H Millar, ... - Journal of Immunotherapy, 2004 - immunotherapy-journal.com
... Introduction: **IGN311** is a fully humanized monoclonal antibody targeting tumors with over-expression of Lewis Y. 60–90% of human carcinomas of epithelial ...
Websuche

Generation, and Characterization of Two Tetravalent CH2 Domain-Deleted CC49 Mabs.
X Wu, J Hopp, D Perret, J Chung, ME Reff, SM ... - Journal of Immunotherapy, 2004 - immunotherapy-journal.com
... Introduction: **IGN311** is a fully humanized monoclonal antibody targeting tumors with over-expression of Lewis Y. 60–90% of human carcinomas of epithelial ...
Websuche

Improved Lytic Potential of a Therapeutic Monoclonal Antibody by Glycoform Engineering.
M Schuster, P Umana, GC Mudde, G Himmler, H ... - Journal of Immunotherapy, 2004 - immunotherapy-journal.com
... Introduction: **IGN311** is a fully humanized monoclonal antibody targeting tumors with over-expression of Lewis Y. 60–90% of human carcinomas of epithelial ...
Websuche

◀ Goooooogle ▶
Ergebnisseite: **Zurück** 1 2 3 4 5 6 **Vorwärts**

IGN311 Suche

Google Startseite - Alles über Google - Über Google Scholar

Google Scholar BETA IGN311 Suche Erweiterte Scholar-Suche Scholar-Einstellungen Scholar-Hilfe

Web-Suche Suche Seiten auf Deutsch

Scholar **Alle Artikel - Zuletzt aufgerufene Artikel** Ergebnisse **1 - 10** von ungefähr **58** für **IGN311**. (**0,19** Sekunden)

Results from a phase I clinical trial with **IGN311**, a fully humanized IgG1 antibody against Lewis Y ...
DV Oruzio, C Aulmann, N Eller, G Mudde, O Obwaller ... - ASCO Meeting Abstracts, 2004 - meeting.ascopubs.org
... Results from a phase I clinical trial with **IGN311**, a fully humanized IgG1 antibody against Lewis Y in patients with solid tumors expressing Lewis Y antigen. ...
Zitiert durch: 3 - Ähnliche Artikel - Websuche

Compensation of endogenous IgG mediated inhibition of antibody-dependent cellular cytotoxicity by ... - Alle 3 Versionen »
A Nechansky, M Schuster, W Jost, P Siegl, S ... - Molecular Immunology, 2007 - Elsevier
... The location of the fucose residue which is not present in the moss-derived glyco-engineered **IGN311** variant IGN314 is encircled. ...
Zitiert durch: 9 - Ähnliche Artikel - Websuche

Improved Effector Functions of a Therapeutic Monoclonal Lewis Y-Specific Antibody by Glycoform ... - Alle 3 Versionen »
M Schuster, P Umana, C Ferrara, P Brunker, C ... - Cancer Research, 2005 - AACR
... The aim of the present study was to produce glycosylation variants of the therapeutic Lewis Y-specific humanized IgG 1 antibody **IGN311** to enhance cell-killing ...
Zitiert durch: 11 - Ähnliche Artikel - Websuche

[ZITATION] Results from a phase I clinical trial with **IGN311**, a fully humanized IgG1 antibody against Lewis Y ...
DV Oruzio, C Aulmann, N Eller... - Proc Am Soc Clin Oncol, 2004
Zitiert durch: 1 - Ähnliche Artikel - Websuche

Anti-Angiogenic and Anti-Cancer Activity of Monoclonal Antibodies to CCL-2/MCP-1 (Monocyte ...
P Kesavan, F McCabe, H Millar, N Stowell, P ... - Journal of Immunotherapy, 2004 - immunotherapy-journal.com
Page 1. **IGN311** mediates the destruction of Lewis Y positive cells by complement activation (CDC) and activation of cellular mediated cytotoxic effects (ADCC). ...
Zitiert durch: 2 - Ähnliche Artikel - Websuche

Combination Human B7. 1/NHS76 and B7. 1/Fc Fusion Protein Immunotherapy and CD25+ T-Regulatory Cell ...
A Liu, P Hu, LA Khawli, AL Epstein - Journal of Immunotherapy, 2004 - immunotherapy-journal.com
... Introduction: **IGN311** is a fully humanized monoclonal antibody targeting tumors with over-expression of Lewis Y. 60–90% of human carcinomas of epithelial ...
Zitiert durch: 1 - Ähnliche Artikel - Websuche

Inhibition of Xenograft Tumor Growth and Down-Regulation of ErbB Receptors by an Antibody Directed ... - Alle 4 Versionen »
H Farhan, C Schuster, M Klinger, E Weisz, G ... - Journal of Pharmacology and Experimental Therapeutics, 2006 - ASPET
... Previous experiments showed that the humanized Lewis Y-specific monoclonal antibody, **IGN311**, reduced ErbB-receptor-mediated stimulation of mitogen-activated ...
Zitiert durch: 2 - Ähnliche Artikel - Websuche

... II, Open Label Trial With the Lewis Y Specific Humanized Monoclonal Antibody **IGN311** in Patients With ...
H Loibner, T Bauernhofer, H Samonigg, P Regitnig, ... - Journal of Immunotherapy, 2006 - immunotherapy-journal.com
... ANTIBODIES A Phase I/II, Open Label Trial With the Lewis Y Specific Humanized Monoclonal Antibody **IGN311** in Patients With Malignant Effusions Hans Loibner 1 , ...
Websuche

[ZITATION] Immunological evaluation of a phase I trial with **IGN311**
G Waxenecker, N Eller, S Stranner, A Obwaller, G ... - AACRMTG, 2005 - American Association for Cancer Research
Websuche

Results from a phase I clinical trial with **IGN311**, a fully humanized IgG1 antibody against Lewis Y ...
P View, E Page, O Template, S Workflow - asco.org
... Results from a phase I clinical trial with **IGN311**, a fully humanized IgG1 antibody against Lewis Y in patients with solid tumors expressing Lewis Y antigen. ...
Im Cache - Websuche

Goooooogle ▶
Ergebnisseite: 1 2 3 4 5 6 **Vorwärts**

IGN311 Suche

Google Startseite - Alles über Google - Über Google Scholar